

PSJ13 Exh 7

**From:** Millward, Joseph  
**Sent:** Fri, 5 Dec 2014 17:13:58 -0500  
**To:** Carlson, Gregory  
**Cc:** Chunderlik, George  
**Subject:** FW: DSCSA Documents  
**Attachments:** Corporate recall procedures.pdf, Outdate\_Damage\_Recall Return\_Policy.pdf, Authentication and Verification Pharmacy Merchandising team.doc, Inventory Control Doc.doc, Product Authentication - Inbound.doc, Product Authentication-Outbound.doc, Quarantined product.doc, Recall Doc.doc, Records Doc.doc

Greg,

George and I along with Matt and possibly Mike will have to review how the existing documents already cover the DSCSA. Then we will have to close any remaining gaps.

Joe

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**From:** Chunderlik, George  
**Sent:** Thursday, December 04, 2014 5:58 PM  
**To:** Millward, Joseph  
**Subject:** DSCSA Documents

Hi Joe,

As a first step in updating our Policies and Procedures for the Drug Supply Chain Security Act I have gone through our existing policies and have attached those that I think may need to be updated to comply.

- Outdate, Damage, Recall Return Policy (currently resides on GE Central in the Policies folder)
- Corporate Recall Procedure (written for ACHC accreditation)

The remaining WORD documents were all written for the VAWD Accreditation and are currently residing on the "S" drive via the following path:

S:\RSC\HBC\VAWD certification\NABP Application docs\Required Policies and Procedures

- Authentication and Verification Pharmacy Merchandising Team
- Inventory Control Doc
- Product Authentication – Inbound
- Product Authentication – Outbound
- Quarantined Product
- Recall Doc
- Records Doc

We can discuss this more on Friday.

Thanks,

George

**Standards Reference: DRX7.7A**

## Giant Eagle Corporate Recall Procedures

### Purpose

To describe the procedures for the management of product recalls.

### Procedure

**Upon notification of a recall or market withdrawal:**

#### Class I Recall:

##### **Processing:**

- **Quality Team reviews documentation:**
  1. Identify the item and run purchase history (6-12 months)
  2. Run current on-hand inventory in stores/warehouse/central fill
  3. Run customer script history (6-12 months)
  4. Notify the Recall Coordinator

##### **Recall:**

- Recall Coordinator reviews the documentation
- Recall Coordinator issues recall notice to stores/warehouse/central fill
- Product is pulled from inventory using the product recall user instructions
- Recalled product is shipped to the Reverse Distributor or as instructed in recall announcement

##### **Customer Contact:**

- Each customer will receive an automated phone call, and one recall letter mailed to the last known address to inform them of the recall and instructions.
- Medication Returns/Exchanges are offered to customer except for controlled drugs (customer directed to contact manufacturer).
- Customers are given the manufacturer phone number for future questions regarding the recall

##### **Billing/Credit**

- The Reverse Distributor will process and invoice the recalled product plus shipping/handling fees
  - \$5 per unit
- Follow standard invoicing per Giant Eagle standard recalls fees (if Direct vendor bill accordingly)
  - \$5 per customer phone call
  - \$5 per customer letter mailed

Created: 07/25/2014 GERX P & P

Revised:

**Standards Reference: DRX7.7A****Class II & III Recall:****Processing:**

- **Quality Team reviews documentation:**
  1. Identify the item and run purchase history (6-12 months)
  2. Run current on-hand inventory in stores/warehouse/central fill
  3. Run customer script history (6-12 months)
  4. Notify the Recall Coordinator

**Recall:**

- Recall Coordinator reviews the documentation
- Recall Coordinator issues recall notice to stores/warehouse/central fill
- Product is pulled from inventory using the product recall user instructions
- Recalled product is shipped to the Reverse Distributor or as instructed in recall announcement

**Customer Contact:**

- None

**Billing/Credit**

- The Reverse Distributor will process and invoice the recalled product plus shipping/handling fees
  - \$5 per unit
  - Follow standard invoicing per Giant Eagle standard recalls fees (if Direct vendor bill accordingly)

**Market Withdrawal:****Processing:**

- **Quality Team reviews documentation:**
  1. Identify the item and run purchase history (6-12 months)
  2. Run current on-hand inventory in stores/warehouse/central fill
  3. Run customer script history (6-12 months)
  4. Notify the Recall Coordinator

**Recall:**

- Recall Coordinator reviews the documentation
- Recall Coordinator issues recall notice to stores/warehouse/central fill
- Product is pulled from inventory using the product recall user instructions
- Recalled product is shipped to the Reverse Distributor or as instructed in recall announcement
- Deactivate item in HOST (Discontinue date and inactivate)
- Initiate a Relay Health Edit "to ensure when a claim is submitted for XXX, the claim is stopped"

Created: 07/25/2014 GERX P &amp; P

Revised:

**Standards Reference: DRX7.7A**

**Customer Contact:**

- None

**Billing/Credit**

- The Reverse Distributor will process and invoice the recalled product plus shipping/handling fees
  - \$5 per unit
  - Follow standard invoicing per Giant Eagle standard recalls fees (if Direct vendor bill accordingly)

Created: 07/25/2014 GERX P & P

Revised:



# Giant Eagle Pharmacy Policy/Procedure

## Outdate, Damage and Recall Return Policy

### Purpose

- To ensure that outdated and/or damaged product is removed from active inventory
- To maintain accurate on-hand counts in our computer system

### Points

- All inventory must be checked for expiring product every month
- All manufacturer products (stock bottles, etc.) that will expire in the current or following month must be removed from active inventory.
- All returned to stock vials/bottles are removed from active inventory at the expiration of the time period defined by the state in which the pharmacy is located
  - PA, OH, and MD – 180 days
  - WV – 90 days
- All damaged and recalled product is removed from active inventory
- The on-hand count in the computer must be updated when inventory is removed
- Store all outdated, damaged and recalled products away from active inventory and follow corporate outdated return procedures
  - **All outdated/damaged controlled substances must be separated from the active inventory, labeled as outdated/damaged, and stored within locked cabinets until returned**

## Procedure

### Steps

- Monthly, each Team Member is assigned a section of the inventory to complete the following
  - Check for expiring product
  - Clean the shelves
  - Update computer on-hand counts for removed products
- All outdated/damaged products are removed from active inventory
- A sign-off sheet is kept to verify each Team Member has completed his/her assigned section(s)
  - **The sign-off sheet is to be posted and each monthly column initialed and dated as completed.**
  - **The completed sign-off sheets are to be placed in the Pharmacy Operations Binder**
- Damaged or recalled products are removed from active inventory as discovered/notified
  - Any additional instructions for recalled products are followed
- Removed products are counted and the on-hand count is updated in the computer
- If any removed product contains a patient label, completely blacken out the patient name and prescription number with a black permanent marker (i.e. "Sharpie") so it cannot be read
- Removed products are stored separately from active inventory in an empty, vial box labeled as "Outdated/Damaged"
  - **All outdated/damaged controlled substances must be separated from the active inventory, labeled as outdated/damaged, and stored within locked cabinets until returned**
- Once per quarter, the removed products are returned following the procedures provided by our outdate service contractor

## Sample Sign-off Sheet

Each Pharmacy Team Member is assigned shelves to complete. The Team Member initials the appropriate monthly column after all expiring product is removed and the shelves have been cleaned.

[illegible][illegible]

Created 02-08-13

Revised: 10-03-13



HBC Service Co. 601 Meadowlands Blvd. Washington PA 15301	
Vendor/Customer Authentication Procedure	Effective Date: September 1, 2014
	Last Revision Dates:

**Procedure:**

Giant Eagle maintains the highest standards in ensuring the integrity, legitimacy, and authenticity of prescription drugs and device purchasing.

**Scope:**

This applies to:

- Pharmacy Category Manager AKA Pharmacy CM
- Pharmacy Assistant Buyer
- Pharmacy Merchandising Manger
- Coordinator of Pharmacy Inventory
- Coordinator of Pharmacy

**Responsibilities:**

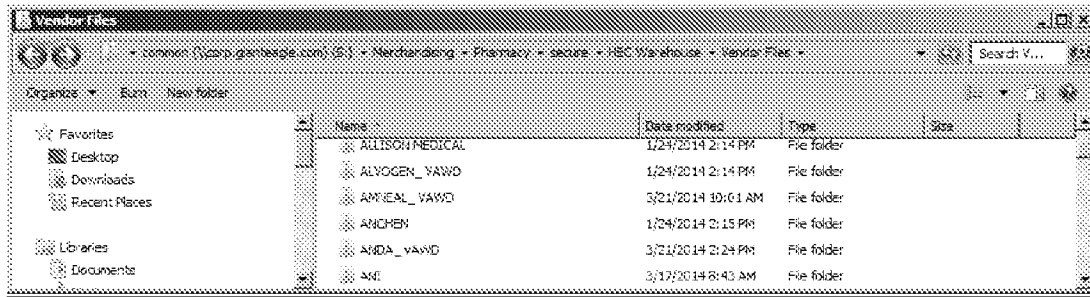
All pharmacy merchandising team members are responsible for ensuring this procedure is adhered to with the most stringent law or regulation.

**Procedure:**

Pharmacy Category Manager, Pharmacy Assistant Buyer, or Pharmacy Merchandising Manager will complete the following steps 1-7:

- 1) Provide all required documentation to vendor
  - a. Cover Letter\_Post VAWD Certification
  - b. Form-Anti-Diversion Letter\_GE
  - c. Form-Vendor Information GE
- 2) Create Vendor File in buying system under an Inactive (I) status

- 3) Create Vendor Folder under S:\Merchandising\Pharmacy\secure\HBC Warehouse\Vendor Files\“Vendor Name”\_VAWD



- 4) Obtain all required information from vendor and save to the appropriate Vendor File and update VAWD\_Vendor\_Information spreadsheet.

Documentation	File Naming Convention*	Requirement
Vendor Information Form	VendorInformation	Mandatory
Proof of Liability Coverage	InsuranceCertificate	Mandatory
<b>BUYING CONTRACTS</b>		
Buying Contract	BuyingContract + “date signed”	Pharmacy CM Discretion
Returned Goods Policy	ReturnedGoodsPolicy	Pharmacy CM Discretion
Confidentiality Agreement	GEConfidentialityAgreement	Pharmacy CM Discretion
Pricing Contracts/ Lists	Variable as Buyer determines	Pharmacy CM Discretion
Confidentiality Agreement	VendorConfidentialityAgreement	Pharmacy CM Discretion
Rebate Program	RebateProgram	Pharmacy CM Discretion
<b>VAWD DOCS</b>		
Vendor Anti-Diversion Letter	AntiDiversionLetter	Mandatory
ADR letter for Vendor	Vendor ADR	Pharmacy CM Discretion
State License for Vendor	“exp date”+State License	Pharmacy CM Discretion
Pennsylvania State License	“exp date”+PAStateLicense	Pharmacy CM Discretion

DEA License	"exp. date" +DEALicense	Pharmacy CM Discretion
Other Licenses or Certifications	Variable as Buyer determines	Pharmacy CM Discretion
Inspections, Reports, 483s	Inspections, Reports, 483s	Pharmacy CM Discretion

\*All Files to be followed by "\_VendorName" unless otherwise stated

- 5) Verify licensure information using the appropriate applicable State or Federal primary source for verification. The date at which the verification takes place will be documented.
- 6) Update vendor Status to Active (A) pending final review and approval by Pharmacy CM  
**Note:** At no time may orders be placed to a vendor that does not meet all requirements as deemed mandatory.
- 7) The first Monday of every month, the Pharmacy Category Manager, Pharmacy Assistant Buyer, or Pharmacy Merchandising Manager will review all vendor licensing for documentation nearing expiration and request updated information from each identified vendor. Should at any time, current documentation on file become expired the affect vendor(s) will immediately be placed into an Inactive status in the purchasing system and inventory may no longer be purchased from that vendor(s).

HBC Service Co. 601 Meadowlands Blvd. Washington PA 15301	
Inventory Controls	Effective Date 8/1/14
Document Control Number 1	Revision Dates

**Overview:**

The HBC Service Company will maintain and comply with all policies contained in this document. Authentication of prescription product orders ,Reporting suspicious prescription product orders, Process for ensuring secure receipt, storage, inventory, transport, and shipping please **\*\*see information on receiving, stocking, selection and transport**

**Scope:**

This applies to:

All HBC Service Company TM's who have access and work in the HBC pharmacy room.

**Responsibilities:**

Warehouse operation manager is responsible for ensuring these policies and procedure is adhered to with the most stringent law or regulation.

**Processes:****Reporting Suspicious prescription product orders**

- HBC Pharmacy group will be contacted by GE Pharmacy team if they suspect any suspicious ordering by a Giant Eagle Pharmacy.
- HBC, as directed by the GE Pharmacy team, will delete or restrict any order that has been identified as suspicious.
- HBC will prepare and communicated any history of suspicious orders to the GE Pharmacy team as requested.
- The GE Pharmacy team will, in conjunction with the HBC Pharmacy information, notify the DEA with in the prescribed 3 day time limit.

**Process for Identifying, recording, and reporting significant losses, thefts, or otherwise missing prescription products:**

Inventory/cycle count schedule

- Generic pharmaceuticals – are cycle counted twice / week
- Name brand pharmaceuticals are counted nightly after selection is completed
- Reserve locations in the general Rx warehouse are counted monthly
- Narcotics cage – pick slots are counted 4x per night – pre selection shifts, 1<sup>st</sup> selection break, Lunch, 2<sup>nd</sup> selection break and end of shift. Narcotic room reserves are counted monthly.

Inventory corrections

- Selection location error correction is completed at the point that they are discovered and counted
- Records of the cycle count adjustments are kept in the Giant Eagle J:/ drive, Pharmacy file monthly

Inventory Audit Trails

- Records of the inventory adjustments are kept on the HBC/Giant Eagle S:/ Drive. They are also kept in the HBC Pharmacy audit too program.

Internal investigation process

Any suspicious pharmaceutical product issues that are discovered by the cycle counter are reported to management, and if further investigation needs to occur a member of Loss Prevention will be contacted. Any controlled substance pharmaceutical issues need to be reported to the DEA within 3 days.

In-transit Losses Thefts

- Inbound – discrepancies are noted at the time of receiving, and Giant Eagle Pharmacy purchasing representative is contacted and notified of the issue.
- Outbound – once a discrepancy is reported, HBC will review shipping reports to ensure that internal outbound shipping reports are accurate. HBC will also review video of the selection area, staging area and loading process in order to determine if all pharmacy totes and pallets were loaded.

Suspicious losses – If HBC pharmacy believes that losses are suspicious – HBC contacts the Giant Eagle Loss Prevention representative and the Giant Eagle Pharmacy Manager and the appropriate report form for the FDA is completed within 3 days.

Significant Loss Threshold -

- Record retention – HBC retains all pharmacy records for a period of 3 years.
- Trash removal – Trash receptacles are inspected prior to them leaving the HBC pharmacy room. The receptacles are under video surveillance during the entire transport and emptying process. The receptacles are then emptied into a sealed compactor.

Process for disposing product containers, labels and packaging – HBC does not dispose of any labels, containers or packaging. HBC only disposes of outer corrugated packaging used in the packaging shipment of pharmaceuticals.

Process for ensuring oldest product is distributed first (FIFO) – The Manhattan WMS system records the receipt date for all inbound Rx products. Those products are stored and are replenished to a pick location according to their receipt date and those methods follow the FIFO method of inventory control.

Process for identifying and handling outdated Rx products –

Items that are outdated are segregated from the regular stock of pharmaceutical items in order to prevent their selection and distribution to stores. Those items that are out of date are then sent to:

CLSMR  
4332 Empire Road  
Fort Worth, TX 76155  
800-967-5952  
DEA: RR0191902

Specified HBC out of date items are sent back to CLS quarterly.

Items that are sent to CLSMR for destruction will be:

- Properly documented by a representative of HBC Pharmacy team
- Packaging of soon-to-be disposed of products will be witnessed and performed by a representative of the HBC Pharmacy team
- HBC Pharmacy inventory will be reconciled by the HBC Pharmacy team representative once the item moves from HBC inventory and into the secure quarantined area.
- Once the items are sent to CLSMR a certificate of destruction will be retained and kept for those items that were destroyed.

Quarantined product – Any product that is suspected to have been tampered with or mistakenly returned to HBC and will be recorded then quarantined in a separate, secure, temperature controlled area within the HBC pharmacy room. Items will remain in quarantine until HBC is given instructions on how to dispose of the product properly.

Document Owner: Matt Rogos	Manager:
Signatures:	Revision Dates

<b>HBC Service Co.</b> <b>601 Meadowlands Blvd</b> <b>Washington PA 15301</b>	
Product Authentication – In bound	Effective Date 8/1/14
Document Control Number	Revision Dates

**Overview:**

HBC will enforce and will adhere to these written SOP's to authenticate inbound pharmaceuticals entering the building.

**Scope:**

This applies to:

Warehouse Operation Manager

Warehouse Associates

**Responsibilities:**

Warehouse operation manager is responsible for ensuring these policies and procedure is adhered to with the most stringent law or regulation.

**Procedures:**

Inbound product authentication policy and procedure:

- Any product that HBC Pharmacy is unable to authenticate the Pedigree, origin or supplier will be quarantined until further instruction.
- Receiving records are kept with the HBC Pharmacy group for a period of 3 years.
- An HBC Supervisor/Manager will be present for each receipt of pharmaceuticals in to the HBC Warehouse. The supervisor is responsible for checking the Bill of Ladings(BOL) to make sure the correct Purchase Orders (PO) are received.
- The HBC Supervisor/Manager inspects the BOL to ensure
  - delivering carrier is accurate with that indicated on the BOL
  - The Purchase Order (PO) on the BOL and the PO on the inbound pallet label are accurate and match
  - Supervisor/Manager note the BOL if there are any discrepancies to the inbound pallets
  - Supervisors/Managers note the BOL if there are damages to pallets and if there are items that cannot be received due to damage



- If all PO's on the BOL match. The BOL's are signed by the Supervisor/Manager and a copy is maintained at the HBC pharmacy office.

#### **Identifying damaged or unfit prescription products**

- When damaged or unfit prescription products are found in the HBC Pharmacy they are taken to the Support coordinator on duty
- The products are systematically taken out of the inventory and quarantined
- The item is inspected in order to determine if there was any suspicious activity causing the damage
- If no suspicious activity is determined the item is segregated and GE Pharmacy department representative is contacted to inform them that the product needs to be returned or destroyed.
- If suspicious activity is determined, HBC Supervision/Management is contacted

#### **Identification of suspicious tampering of Pharmaceuticals**

- If HBC Support Coordinators believe that they have discovered pharmaceuticals that have been tampered with in the HBC pharmacy, Supervision or Management is contacted immediately.
- If HBC Supervision/Management also determine that the item has been tampered with a member of Giant Eagle Loss Prevention is contacted and called into further investigate.
- Giant Eagle Pharmacy department representative is also contacted and notified of the ongoing investigation.
- If the pharmacy item is a narcotic, GE Pharmacy department representative is contacted and a report to notify the DEA within 3 days.
- The item that was tampered with will be segregated and stored until authorization from the DEA is granted to dispose of the item

#### **Preventing Suspicious Activity**

- HBC attempts to prevent any suspicious activity during operations by 7/24/365 video surveillance. The video is stored on site for 30 days.
- HBC also cycle counts inventory in the pharmacy room and an inspection of the product is completed when cycle counts are performed.
- All HBC TM's are encouraged to notify Support Coordinators, Supervisors, or Managers if they believe there is an item that has been tampered with.

#### **Receiving Procedures**

- All inbound items, when received into HBC pharmacy inventory have the following information recorded:
- PO Number – recorded and kept with GE Pharmacy
- Sales Invoice Number – recorded and kept with GE Pharmacy

- Date of purchase - recorded and kept with GE Pharmacy
- Lot Number - recorded and kept with HBC Pharmacy
- Expiration Date - recorded and kept with HBC Pharmacy
- Contact information of the supplier – Name, Address, Telephone, Email address from the source from which the product was ordered is kept with GE Pharmacy.

#### **Receiving Narcotics at HBC**

- Narcotics that are delivered to HBC will enter the building at receiving Door 50 Only
- Narcotics will be identified at the point of entry and will be directly taken to the HBC Narcotics cage located in the pharmacy room
- Narcotics that are received at HBC will only be received and processed in the HBC narcotics cage and will not be received in the normal pharmacy receiving area

#### **Receiving Non-Narcotics at HBC**

- Non-narcotic pharmaceuticals will be delivered to HBC and will enter the building at receiving Door 50 Only
- Non- Narcotics will be identified at point of entry and will be taken directly to the HBC pharmacy receiving area located adjacent to the HBC pharmacy room

Document Owner: Matt Rogos	Manager:
Signatures:	Revision Dates

HBC Service Co. 601 Meadowlands Blvd. Washington PA 15301	
Product Authentication-Outbound	Effective Date 8/1/14
Document Control Number	Revision Dates

**Overview:**

The HBC warehouse maintains the highest standards in ensuring that the product leaving HBC pharmacy is secure, damage free and in the best condition possible.

**Scope:**

This applies to:

- Warehouse operation manager
- Warehouse operation manager assistant

**Responsibilities:**

- Upon completion of selection, completed totes are stacked neatly onto outbound pallets and prepared for shipping.
- The Support Coordinator ensures that the narcotic totes are properly combined with the generic totes by pharmacy number
- The Support Coordinator scans each tote label with an RF gun and attaches all tote labels on the pallet to a pallet license plate number(LPN)
- The tote count per pallet is then recorded and documentation is printed for shipping verification
- When the outbound carrier arrives at HBC, a Supervisor/Manager is called to supervise the loading of the pharmacy pallets.
- Paperwork is taken to the loading door, and the supervisor and outbound driver verify the count of totes on each pallet as well as the number of pallets to be taken.
- Pallets/totes are also inspected at this time for any sign of visual damage or tampering.
- The driver's and Supervisor/Manager's signature is written on the BOL indicating that the counts are correct

- If the counts are not correct, the Supervisor Manager will investigate to determine why the count on the outbound paperwork differs from the actual counts on the pallets.
- Video surveillance monitoring covers the path from the pharmacy room to the loading door.

#### Temperature controlled shipments

- HBC ships all temperature controlled items in cooler totes. Cooler totes contain insulation in the tote and are packed in the proper manner at the time of selection.

#### Procedure:

Document Owner: Matt Rogos	Manager:
Signatures:	Revision Dates

HBC Service Co. 601 Meadowlands Blvd. Washington PA 15301	
Quarantined Product	Effective Date 8/1/14
Document Control Number 1	Revision Dates

**Policy:**

The policy defines the procedures for quarantining pharmaceuticals that are damaged, tampered, recalled, or otherwise unfit for sale to GE Pharmacies.

**Scope:**

This applies to:

- Warehouse operation manager
- HBC Support Coordinators

**Responsibilities:**

Warehouse operation manager is responsible for ensuring this policy and procedure is adhered to with the most stringent law or regulation.

**Procedure:**Qualifications for HBC pharmaceuticals to be Quarantined

- Recalled pharmaceuticals
- Damaged Pharmaceuticals
- Pharmaceuticals that are suspected to have been tampered
- Pharmaceuticals that have been mistakenly returned to the HBC Pharmacy
- Pharmaceuticals that are passed the products expiration date
- Pharmaceuticals that are counterfeit or suspected to be counterfeit

Quarantined Pharmaceuticals

- Any pharmaceutical that is meant to be quarantined, will be:

- Recorded according to Item, description, Lot Number, and quantity
- Placed in a secure, locked room
- Placed in a locked filing cabinet inside the secure, locked room
- Will remain there until instructions for disposal are given to HBC Pharmacy by GE pharmacy group
- Any quarantined product will be removed from HBC and destroyed properly.

#### Quarantined Narcotics

- Any narcotic that is meant to be quarantined, will be:
  - Recorded according to Item, description, Lot Number, and quantity
  - Placed in the HBC narcotics cage which is locked, security camera monitored, and is also secured by Sonitrol alarm system
  - The narcotic is also placed in a locked filing cabinet inside the narcotics cage
  - Will remain there until instructions for disposal are given to HBC Pharmacy by GE pharmacy group

Document Owner: Matt Rogos	Manager:
Signatures:	Revision Dates

HBC Service Co. 601 Meadowlands Blvd. Washington PA 15301	
Recall	Effective Date 8/1/14
Document Control Number 1	Revision Dates

**Policy:**

To ensure that recalled product is removed from HBC Pharmacy inventory.

**Scope:**

- All inventory must be checked for expiring product every month
- All manufacturer products (stock bottles, etc.) that will expire in the current or following month must be removed from active inventory.
- All returned to stock vials/bottles are removed from active inventory at the expiration of the time period defined by the state in which the pharmacy is located
  - PA, OH, and MD – 180 days
  - WV – 30 days
- All damaged and recalled product is removed from active inventory
- The on-hand count in the computer must be updated when inventory is removed
- Store all outdated, damaged and recalled products away from active inventory and follow corporate outdated return procedures
  - All outdated/damaged controlled substances must be separated from the active inventory, labeled as outdated/damaged, and stored within locked cabinets until returned

**Responsibility:**

- GE Pharmacy Group
- HBC Warehouse Operations Manager
- HBC Supervisors/Managers
- HBC Support Coordinators, assigned to HBC Pharmacy

**Procedure:**

- In the event of a pharmaceutical recall HBC pharmacy group receives an email detailing the specifics of the recall
- Product Name, Item number and Lot number are communicated to the HBC pharmacy
- HBC Pharmacy department, upon receipt of the recall email, will check the inventory to determine if the product or lot numbers are in the current inventory.
- If the specified item and lot number are found recalled products are removed from active inventory as discovered/notified
  - Any additional instructions for recalled products are followed
- Removed products are counted and the on-hand count is updated in the computer and communicated to the GE Pharmacy group.
- Removed products are stored separately from active inventory in an empty, vial box labeled as "Outdated/Damaged" and are stored in a quarantined location at HBC Pharmacy.
  - All outdated/damaged controlled substances must be separated from the active inventory, labeled as outdated/damaged, and stored within locked cabinets until returned
- Once per quarter, the removed products are returned following the procedures provided by our outdate service contractor, CLSMR.
- A certification of proper destruction will also need to be kept for any pharmaceutical that is recalled.

Document Owner: Matt Rogos	Manager:
Signatures:	Revision Dates





HBC Service Co. 601 Meadowlands Blvd. Washington PA 15301	
Records	Effective Date 8/1/14
Document Control Number 1	Revision Dates

**Overview:**

It is the Policy of Giant Eagle to generate and retain only those papers, records, and electronically stored data which are required for the effective operation of our Company and to meet our obligations to our customers, employees, the government, the courts, and our shareholders.

**Scope:**

This applies to everyone who generates, receives, or stores information in any form is responsible to implement this Policy.

**Responsibilities:**

All parties involved with scope are responsible for ensuring this policy and procedure is adhered to with the most stringent law or regulation.

**Procedures- E-mail and Voice Mail:**

- The Company maintains an e-mail and voice mail system to assist in the conduct of its business. These systems, and the information retained in these systems, remain at all times the property of the Company
- Employees should be aware that they have no legal right to privacy in information transmitted in e-mail or voice mail. While passwords may be used or even recommended for security, they do not guarantee confidentiality. Even after an e-mail is deleted, a copy may exist in the computer memory which can be recalled
- E-mail and voice mail should not be used to store information for future use or for indefinite periods. Information which must be stored for future use should be copied to a permanent record and filed, and the electronic record deleted. Employees should clean out electronic mailboxes regularly. The computer will automatically delete e-mail messages according to the Electronic Communications Policy

**Procedures- Records kept in office at company headquarters:**

- Only those records of current use to the employee or which involve ongoing operations should be maintained in the office.

- Records involved in ongoing lawsuits should be kept in the office and not sent to storage until cleared by the Legal Department.
- All in-office records should be reviewed periodically. Superseded or outdated documents and anything more than two years old should be destroyed or, where the policy requires a longer period, sent to the main file room or to long term storage.
- Once a document has been finalized, discard all drafts.
- Avoid keeping more than one copy of any document. Employees should not keep duplicate "chronological" files of every piece of paper generated.
- Notebooks and presentation material from sales meetings, conventions and trade association meetings should not be sent to long term storage. These documents should be kept for reference in the office only if the information they contain is not readily available from other sources.
- When an employee ceases employment with the Company, do not ship his or her files to storage. Have the employee assuming that work go through all files and decide what to store. All original personnel records should be sent to the designated department for inclusion in the Personnel Files. Any copies retained must be discarded in accordance with the retention guidelines applicable to original documents.
- Before sending any file to storage, discard duplicates, copies, and courtesy copies

**Procedures- Business information for personal use:**

In certain circumstances, an employee may possess documents that contain both business and personal information or which are business documents kept by the employee for personal use. These may include:

- desk and appointment calendars
- day-timers
- sales visit records
- copies of office reports and memoranda kept for personal information

Whether these documents are kept in the office or at home, they are nonetheless subject to this Policy and should be discarded **after two years**. Each employee who possesses this kind of document is responsible to follow and apply this Policy to discard those documents at the recommended time. (Exceptions may be allowed on a case-by-case basis if approved by the legal department.)

Pursuant to the Electronic Communications Policy, outlook calendars will be automatically deleted after 13 months.

**Procedures- Long Term Storage:**

Documents should be sent to long term storage and not discarded only in the following situations:

- The information must be retained for a certain period because of state or federal law;
- The information relates to corporate governance and is necessary to the ongoing or future operations of the Company;

- An investigation or litigation is pending or anticipated regarding the topic of the documents; or
- The period in which litigation relating to the documents may be brought has not yet run.

**Procedures- Electronic Records-“Cyber Documents”:**

All of the above rules apply equally to documents which exist on paper and to those which exist only on computer diskette or hard drive ("cyber documents"). When discarding any paper document under this policy, also be sure to delete the cyber document.

**Procedures-Special Exception for Investigations:**

- Any person having knowledge of an ongoing or anticipated investigation by any state or federal entity or an actual or anticipated legal proceeding in which documents on this chart are relevant should immediately bring that information to the attention of the legal department so that appropriate action can be taken to preserve any documents which would otherwise be discarded in the ordinary course.
- Pursuant to the established business practices of the Company, once any legal action or investigation by or against any internal entity, third party or government entity is reasonably anticipated, all documents within the expected scope of that inquiry must be retained notwithstanding anything else in this policy. This duty to retain continues until you are informed by the Legal Department that the matter is resolved.

**Other Details:**

Chart containing the recommended retention periods for various classes of documents in long term storage. This chart applies to both hard copy and computer records of them. The retention guidelines on the following chart apply not only to documents generated for the business of Giant Eagle, Inc. itself, but also to those documents which relate to independent stores or subsidiaries where those documents are handled or maintained by Giant Eagle personnel.

DOCUMENT CODE AND CLASS	TYPES OF DOCUMENTS	RETAIN FOR:	REASON
PS  Pharmacy Services	Billing Records – Credit Memoranda, Credit-Charge-Transfer Sheets; Reimbursement Records	7 years	Medicare, PACE audit requires 3 years
	Daily Transaction Logs; Customer Signature/Insurance Logs	6 years	Backup for audit of reimbursement by Medicare, PACE
	Pseudoephedrine Sales Records and Logs	WV – 5 years, everywhere else, 2 years	21 U.S.C. §830-(2 years)  WV ADC §15-11-8 (5

			years)
	Controlled Substance Inventory and Distribution Records DEA Theft/Loss Reports; DEA Drug Destruction; Narcotic Controlled Prescription Files	5 years	21 C.F.R. §1304.04 requires 2 years minimum
	Records of Complaint or Inquiry about Pharmaceuticals Inspection Reports; Poison/Syringe Exempt Narcotic Log; Returns of out-of-date	3 years	In case of claims or inquiries
	Recall Notices, correspondence and contacts with customers	3 years	In case of claims or inquiries
	Prescription Records (filled prescriptions, patient profiles, purged prescription microfiche)	6 years	All customer-related information must be kept for 6 years – HIPAA. PA-2 year minimum. 49 Pa. Code §27.19(g)(4)
	Medicare Part D Records	10 years	To conform with contract obligation with Plan Sponsor

DOCUMENT CODE AND CLASS	TYPES OF DOCUMENTS	RETAIN FOR:	REASON
PS Pharmacy Services	Hard Copies of Prescriptions – Medicare	10 years	Contractual Obligation with Plan Sponsor
	Hard copies of prescriptions*, non-Medicare	PA – 2 ½ years OH – 3 ½ years	State requirements 49 Pa. Code §27.14(c), §27.18(b)(4) (hard

*If state permits electronic record of prescriptions, follow state law for retention period for the computerized copy.		WV, MD – 5 ½ years	copies) OH Code §4729.37 WVADC §60A-8-7 MD Health Code §12-403(b)(13)
	Correspondence and Requests for Patient Profiles (subpoena served)	2 years after last response	To prove compliance with court order
	Correspondence and Requests, no subpoena	1 year from date provided	No follow up needed
	Records of the disclosure of protected health information to third parties other than for treatment purposes	6 years	45 C.F.R. §164.530(j) 45 C.F.R. §164.528
	HIPAA Authorizations	6 years	45 C.F.R. §164.530(j)
	HIPAA Policies	6 years	45 C.F.R. §164.530(j)
	HIPAA Security Documents	6 years	45 C.F.R. parts 160 and 164, §160.524
	HIPAA Privacy Documents including Notices of Privacy Practices	6 years	45 C.F.R. §164.530(j)

Document Owner: Matt Rogos	Manager:
Signatures:	Revision Dates

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